



Billing Code: 4150-41P

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Meeting of the Advisory Committee on Blood and Tissue Safety and Availability**

**AGENCY:** Department of Health and Human Services, Office of the Secretary, Office of the Assistant Secretary for Health.

**ACTION:** Notice.

**SUMMARY:** As stipulated by the Federal Advisory Committee Act, the U.S. Department of Health and Human Services is hereby giving notice that the Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA) will hold a meeting. The meeting will be open to the public.

**DATES:** The meeting will take place Tuesday April 7, 2105, from 8:00 a.m. – 4:00 p.m. and Wednesday April 8, 2015, from 8:00 a.m. – 3:30 p.m.

**ADDRESSES:** NIH Conference Room, 5635 Fishers Lane, Rockville, MD 20892.

**FOR FURTHER INFORMATION CONTACT:** Mr. James Berger, Designated Federal Officer for the ACBTSA, Senior Advisor for Blood and Tissue Policy, Office of the Assistant Secretary for Health, Department of Health and Human Services, 1101 Wootton Parkway, Suite 250, Rockville, MD 20852. Phone: (240) 453-8803; Fax (240) 453-8456; E-mail [ACBTSA@hhs.gov](mailto:ACBTSA@hhs.gov)

**SUPPLEMENTARY INFORMATION:** The ACBTSA provides advice to the Secretary through the Assistant Secretary for Health. The Committee advises on a range of policy issues to include: (1) identification of public health issues through surveillance of blood and tissue safety issues with national biovigilance data tools; (2) identification of public health issues that affect availability of blood, blood products, and tissues; (3) broad public health, ethical and legal issues related to the safety of blood, blood products, and tissues; (4) the impact of various economic factors (e.g., product cost and supply) on safety and availability of blood, blood products, and tissues; (5) risk communications related to blood transfusion and tissue transplantation; and (6) identification of infectious disease transmission issues for blood, organs, blood stem cells and tissues. The Committee has met regularly since its establishment in 1997.

The ACBTSA has made previous recommendations on the need to improve tissue tracking and traceability. These recommendations focused on tracking adverse events, creating a unique identifier for each donor, and improving patient outcomes. Past recommendations made by the ACBTSA may be viewed at [www.hhs.gov/bloodsafety](http://www.hhs.gov/bloodsafety).

The focus of the meeting will be to address current issues in tracking and traceability of tissue recovered from deceased donors. The discussion will focus on pertinent federal and state regulations, other mechanisms that impact tissue tracking and traceability, and current gaps in this area. Presenters will represent a wide range of government and non-government stakeholders, including federal agencies, accreditation organizations, tissue and eye banks, healthcare facilities, and medical practitioners.

The public will have an opportunity to present their views to the Committee during a public comment session scheduled for April 8, 2015. Comments will be limited to five minutes per

speaker and must be pertinent to the discussion. Pre-registration is required for participation in the public comment session. Any member of the public who would like to participate in this session is encouraged to contact the Designated Federal Officer at his/her earliest convenience to register for time (limited to 5 minutes) ; registration must be completed prior to close of business on April 1, 2015. If it is not possible to provide 30 copies of the material to be distributed at the meeting, then individuals are requested to provide a minimum of one (1) copy of the document(s) to be distributed prior to the close of business on April 1, 2015. It is also requested that any member of the public who wishes to provide comments to the Committee utilizing electronic data projection submit the necessary material to the Designated Federal Officer prior to the close of business on April 1, 2015.

**Dated: January 22, 2015.**

James J. Berger,

Senior Advisor for Blood and Tissue Safety Policy.